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EXAMINER
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MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/002,933

Applicant(s)

LEE ET AL.

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-23 and 26 is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-15, 24, 25 and 27-32 is/are rejected.
- 7) ☒ Claim(s) 4-8 and 16-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al (U.S. Patent No. 5,728,748).

Sun et al teaches a method of sterilizing a medical implant wherein the implant is placed within a container, the container evacuated and then repressurized with an inert gas. The packaged implant is irradiated with e-beam radiation. See col.4, lines 22-28 and lines 33-41. The container of Sun et al is disclosed to be air-tight (col.4, lines 34-36). The dose of radiation is 2.5 Mrad (col.7, lines 64-65), which is “about 3” Mrads.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1744

2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al.

Sun et al does not specify a treatment time. However, treatment time is known in the art to be a result effective variable. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the irradiation time based upon dose rate, desired dose, and the material being treated, as is customary in the art.

7. Claims 1-3, 9-11, 13-15, 24, 25, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (U.S. Patent No. 5,849,846) in view of Sun et al.

Chen et al teaches a method of sterilizing a medical device component wherein the component (e.g. dilation catheter tubing material) is irradiated with an electron beam (col.9, lines 21-45) so as to increase the burst strength, fatigue strength, and burst pressure. Chen et al is silent as to whether the e-beam radiation sterilizes the component. However, Sun et al teaches that e-beam radiation is effective in sterilizing polymeric materials. As the component of Chen

Art Unit: 1744

et al will have to eventually undergo sterilization before use and since it is fabricated from a polymeric material like the components of Sun et al, one of ordinary skill in the art would have found it obvious to use the e-beam sterilization of Chen et al to both improve the performance characteristics of the component and to sterilize the component.

Although Chen et al does not disclose treating the component within a sealed, evacuated container, Sun et al teaches a method of sterilizing a medical implant wherein the implant is placed within an air-tight container, the container evacuated and then repressurized with an inert gas. As Sun et al discloses that removing oxygen from the environment of the implant is necessary to prevent oxidation of the implant, it would have been an obvious step in the method of Chen et al. See col.4, lines 58-65).

Chen et al is silent with respect to sterilization dose. Sun et al, however, teaches that 2.5 Mrads is necessary to achieve sterilization (which is "about 3" Mrads). It would have been obvious to use an amount of radiation sufficient to achieve sterilization in the method of Chen et al with Sun et al. The combination of Chen et al with Sun et al does not specify a treatment time. However, treatment time is known in the art to be a result effective variable. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the irradiation time based upon dose rate, desired dose, and the material being treated, as is customary in the art.

8. Claims 12, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al in view of Sun et al as applied to claims 1 and 27 above, and further in view of Avellanet (U.S. Patent No. 5,733,496).

Chen et al teaches the application of electron beam radiation to polymeric catheter

Art Unit: 1744

balloons but does not teach balloons made of the instant materials. However, Avellanet teaches irradiating catheter balloons made of polyether block amide (PEBAX) and PTFE. See col.3, lines 10 and 17; lines 46-48. As these materials are known both to be used in catheter balloons and to be capable of being irradiated, it would have been obvious to one of ordinary skill in the art to apply the method of Chen et al with Sun et al to catheter balloons made of PEBAX or PTFE.

#### *Allowable Subject Matter*

9. Claims 21-23 and 26 are allowed.
10. Claims 4-8 and 16-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. The following is a statement of reasons for the indication of allowable subject matter:  
Although Sun et al teaches irradiating polymeric medical devices in an inert gas atmosphere and Chen et al teaches irradiating catheter balloons, neither teach or suggest purging a medical device or balloon catheter and filling it with an inert gas before irradiation.

#### *Conclusion*


12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Washio et al (abstract of JP 404085340A) teaches the known use of electron beam irradiation to simultaneously sterilize and polymerize polymeric medical materials.

Art Unit: 1744

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387 until December 15, 2003. After December 15, 2003 the examiner can be reached at 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920 or at 571-272-1281 after December 15, 2003. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
3 November 2003